

JAN 7 1997

**510(k) Summary of Safety and Effectiveness**

July 3, 1996

K962648

**Submitter Information**

Ohmeda Inc.  
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**Product Name**

Proprietary: Ohmeda Model 5330 Anesthetic Agent Monitor  
Common: Anesthetic Gas Analyzer  
Classification: Anesthetic Gas Analyzer, enflurane -  
(73CBO/21CFR868.1500 Class II)  
Anesthetic Gas Analyzer, halothane -  
(73CBS/21CFR868.1620 Class II)

**Predicate Devices**

The predicate device is the current version of the same device, the Ohmeda Model 5330 Anesthetic Agent Monitor (4 agent version), 510 (k) # K931439, and the previous version which was the Ohmeda Model 5330 Anesthetic Agent Monitor (3 agent version), 510(k) #K890606. These predicate devices have the same performance specifications as the five agent version being proposed, they just monitor fewer agents. Another predicate device is the Ohmeda Model 5250 RGM Monitor, # K920590, which features an anesthetic agent monitor. The 5250 can monitor sevoflurane. The Ohmeda Model 5330 Anesthetic Agent Monitor (4 agent version) has the hardware capability to monitor sevoflurane, but it is not enabled for the U.S. market. Additionally, the Ohmeda Model 5330 Anesthetic Agent Monitor (5 agent version) is commercially distributed outside the U.S., with emphasis in Europe and Japan.

**Device Description**

The Ohmeda Model 5330 Anesthetic Agent Monitor is a benchtop instrument which draws a continuous flow of sample gas from a patient's anesthesia circuit. The sample is then drawn through a measurement chamber where agent concentration is measured. Measured values are displayed as numbers and as a graph on the illuminated display panel on the front of the unit. The unit is operated by push buttons on the front panel. The major functional subsystems of the device

are the power supply, the pneumatic system, the measurement chamber, the electronics and the software. Power is supplied by a power cord connected to the AC line. There is no internal battery. AC power is conditioned internally by the power supply subassembly. The pneumatic system draws sample gas into the device through a moisture collection system. The sample then enters the measurement chamber, which is a cavity within the optical bench assembly. The sample is then exhausted out the back of the unit. The measurement cavity allows infrared light to be passed through the sample so a detector on the other side of the sample can measure the amount of absorption. The infrared light source consists of a coiled resistive metal element which radiates a relatively wide spectrum of infrared. Two infrared optical filters rotate on a wheel in the optical path, providing alternating wavelengths of illumination through the sample. The amount of transmitted infrared light is measured with an optical detector. By using the detected levels of transmitted infrared light at the two alternating wavelengths, anesthetic agent concentrations can be calculated. The electronic system consists of an analog circuit board and a digital circuit board. The analog board takes electrical signals from the measurement chamber and conditions them so measurement calculations can be performed. The digital circuit board digitizes the conditioned analog signals and performs measurement calculations. Proprietary software algorithms are used to calculate measured concentrations of anesthetic agent in the sample gas.

### **Intended Use**

The Ohmeda Model 5330 Anesthetic Agent Monitor is intended for general hospital or clinical use by medical professionals whenever it is desired to monitor concentrations of anesthetic gas. The agents monitored include isoflurane, endoflurane, halothane, desflurane and sevoflurane. The need to monitor these anesthetic agents is most commonly encountered in the operating room during administration of anesthesia. It is available for sale only by or on the order of a licensed medical practitioner

### **Technological Comparison to Predicate Device**

No hardware changes are necessary for the addition of sevoflurane measurement capability. The existing measurement chamber configuration is sufficient to accommodate the measurement method. Therefore the five agent version will appear physically identical to the current four agent version as far as the user is concerned with the exception that the operating menu will now allow for sevoflurane measurement. All specifications for existing features on the current version will be unaffected by the addition of sevoflurane.